

JUL 25 2001

K011968

SECTION 2.0 – SUMMARY OF SAFETY AND EFFECTIVENESS

June 22, 2001

2.1 General Information

2.1.1 Company Name, Address, and Telephone Number

Lake Region Manufacturing, Inc. (LRM)
340 Lake Hazeltine Drive
Chaska, MN 55318
Telephone: (952) 448-5111 Fax: (952) 448-3441

Contact Name: Jeff Pumper
Quality Assurance Engineer

2.1.2 Device Trade Name/Proprietary Name

LRM produces guidewires on an OEM basis for other manufacturers, kit assemblers, and distributors. Consequently there are a large number of trade and proprietary names not including or associated with LRM. LRM has no proprietary names of its own to be included with this submission.

2.1.3 Device Common Names/Usual Names and Classification Names

These devices are commonly known as coronary catheter guidewires. The current classification names and product codes are Wire, Guide, Catheter (74DQX).

2.1.4 Establishment Registration Number: 2126666

2.1.5 Classification of Devices

Catheter guidewires have been classified as Class II devices by the Circulatory Systems Devices Panel (reference 21 CFR 870.1330).

2.1.6 Applicability of Performance Standards

LRM has determined that no mandatory performance standards have been established for these devices under Section 514 of the Medical Amendments to Federal Food, Drug, and Cosmetic Act or by any subsequent regulatory action. LRM has also determined that there are no applicable voluntary standards.

2.2 Labels, Labeling, and Advertising

LRM produces cardiovascular and vascular guidewires on an OEM basis for other manufacturers, kit assemblers, and distributors. There is no direct distribution by

LRM. Changes to the customer controlled labels, labeling, or promotional material are at their discretion, including the resolution of any resulting regulatory obligations. A fraction of the total production bears LRM controlled labels and labeling.

2.3 Statement of Availability

This summary is being included in the Premarket Notification submission in lieu of a statement of availability.

2.4 Device Description

2.4.1 Utilizing a proprietary process, LRM produces a PTFE coated stainless steel steerable core. The proximal portion of the core wire is coated with PTFE to provide lubricity and improve wire handling. A platinum alloy coil, placed within the confines of the outer coil and over-wrapping the ribbon section, provides radiopacity in the distal tip. The coils are secured in their location by solder, which is attached to the core. The proximal end of the outer coil is attached to the core with braze, and the distal end has a mid-point of the outer coil which is attached to the core with solder. On the models with markers, two additional radiopaque markers that are .009" platinum coils in a 5mm length are provided. The distal portion may be either a 30 cm long stainless steel coil with a 2 cm long inner platinum coil to provide radiopacity or a 30 cm long platinum coil (for radiopacity). The product is offered with a shapeable straight tip or in a preshaped configuration. The guidewires are coated with MDX (silicone). The guidewires are bound by the following parameters:

Outside Diameter:	.014" - .018"
Lengths:	175cm – 300cm
Tips:	Straight or shaped with various tip flexibilities
Flexibility:	Floppy to Support

2.4.2 Engineering Specifications

The design specifications are the same for the proposed device as they are for the LRM predicate device [reference 510(k) K970376]. The finished devices must meet the same basic design criteria.

2.5 Substantial Equivalence Data

2.5.1 Background Information

The table below lists the differences between the predicate device and the proposed device. Testing was done to ensure the changes to the device met the predetermined acceptance criteria.

Item	Proposed Device Differences from LRM Predicate cleared under 510(k) K970376
Raw Materials	Core: No change Outer Coil: No change Inner Coil: No change Marker coil bands: Addition of marker coil bands. However the raw material used is the same as the raw material used to manufacture the inner coil. Extension system: No change
Assembly Process	No significant change to assembly processes
Physical Characteristics	The guidewire will have two sections of PTFE removed to aid in positioning.
Labeling/IFU	The only change to the label or IFU will be to reference the slight design modifications that aid the physician in determining placement of the guidewire {marker band coils and proximal marker (PTFE removed sections)}.
Intended Use	No change to intended use
Anatomical Sites	No change
Target Population	No change
Performance Testing	No change
Safety Characteristics	No change
Biocompatibility	No change
Risk Analysis	No change

In order to demonstrate equivalence of the proposed device, LRM performed testing to established requirements listed in FDA guidance document entitled Coronary and Cerebrovascular Guidewire Guidance, issued January 1995, and ISO 11070 Sterile Single-use Intravascular Catheter Introducers. Additionally, internal test protocol requirements were utilized. Configurations, including straight and shaped distal tips were inspected to established criteria. These parts were produced following current manufacturing processes and procedures.

2.5.2 Test Data

Test pieces were tested and inspected according to established specific inspection criteria requirements for visual/tactile, dimensional and mechanical attributes.

The following tests were performed:

2.5.2.1 Visual: Assess the product for visual appearance per established criteria.

2.5.2.2 Dimensional Measurement – Outside Diameter of Core Body with PTFE coating: Micrometer measurement of the outside diameter of the product at multiple body points.

- 2.5.2.3 PTFE Coating Durability: Measures the ability of the coating to adhere to the core wire material.
- 2.5.2.4 Silicone Adhesion: Assess coating adherence when wire is subjected to wire flexure and tested in a powder.
- 2.5.2.5 Lubricity: Measures the force required to insert and withdraw the guidewire from a shaped catheter lumen.
- 2.5.2.6 Pull Test: Measures the strength of materials and joints in the guidewire.
- 2.5.2.7 Torque Control: Assess guidewire rotational control (clockwise or counter clockwise) to allow placement of the distal tip at a desired location in a 360° radius when controlled from the proximal end of the guidewire.
- 2.5.2.8 Linear Stiffness: Assess the flexibility of the distal tip form of the product.
- 2.5.2.9 Lateral Stiffness: Measures stiffness / flexibility of the guidewire from distal tip through to the guidewire body.
- 2.5.2.10 Radiopacity: Assess the ability of the device to be seen under fluoroscopy, when simulating a density of body mass.
- 2.5.2.11 Corrosion Resistance: Assess the material against resistance to oxidation over a period of time.
- 2.5.2.12 Tip Shape Memory/Retention: Assess the tip form after repeated exposure to a tortuous path.
- 2.5.2.13 Extension Joint Coupling: Assess ease of joint connection.
- 2.5.2.14 Wire Flexure: Assess the distal section and guidewire body for coating damage and guidewire breakage after repeated flexure of the product.
- 2.5.2.15 Wire Fracture Test: Assess the guidewire for breakage after wrapping the distal portion of the guidewire around a mandrel 10X the diameter of the product.
- 2.5.2.16 Combined Load: Assess the torsional integrity of the guidewire by applying a load on one end of the guidewire and torque to the opposite end of the guidewire.

RESULTS: ALL TEST RESULTS WERE WITHIN PRESCRIBED SPECIFICATION LIMITS.
--

2.6 Qualification and Biocompatibility Test Data

2.6.1 Design Control

LRM is in conformance with the design control procedure requirements as specified in 21 CFR 820.30. Risk analysis was completed by means of a Failure Mode and Effect Analysis (FMEA) and all verification and validation activities resulted in the ability to demonstrate that the predetermined acceptance criteria were met.

2.6.2 Material/Product/Process Qualification

LRM has formal quality systems in place to assure that the proposed PTCA steerable product will remain equivalent to the predicate product, and that the changes will not have an adverse affect on the safe and effective use of the product. The quality systems include Engineering Change Order Review, Material Qualification, Product Qualification, and Process Qualification. These controls are applied to each product size/group.

2.6.3 Biocompatibility Testing

Biocompatibility testing has been performed on the material components of this device. This testing, along with a market history of proven biocompatibility establishes acceptable biocompatibility for this device.

2.7 Packaging and Sterilization Information

LRM produces guidewires on an OEM basis for other manufacturers, kit assemblers, and distributors. There is no direct distribution by LRM. A portion of the production is private label, sterile packaged to customer specifications, a fraction of that product is provided sterile to the customer.

The single packaged PTCA steerable guidewire is placed in a dispenser and then into a Tyvek®/poly pouch. The packaged product may be packaged as five or ten pouchs in a shelf carton, which are typical packaging configurations.

There will be no changes to the sterilization process for the portion of packaged product shipped sterile to the customer. For the product that is shipped bulk, the packaging design and sterilization process parameters are the customer's responsibility. LRM will not recommend that its customers modify their packaging or sterilization procedures as a result of this submission.

2.8 Intended Use Statement

For use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.

NOTE: The modification of this device does not alter its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2001

Mr. Jeff Pumper
Lake Region Manufacturing, Inc.
340 Lake Hazeltine Drive
Chaska, MN 55318-1029

Re: K011968
Steerable PTCA Guidewire
Regulation Number: 870.1330
Regulatory Class: II (two)
Product Code: DQX
Dated: June 22, 2001
Received: June 25, 2001

Dear Mr. Pumper:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the

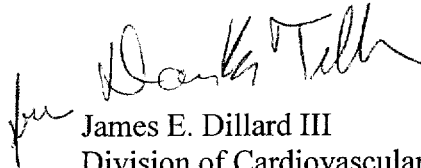
Page 2 - Mr. Jeff Pumper

Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



James E. Dillard III
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): Unknown

Device Name: PTCA Steerable Guidewires

Indications for Use:

For use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE
IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
Division of Cardiovascular & Respiratory Devices
510(k) Number K019682

Prescription Use X Or Over-The-Counter Use _____
(PER 21 CFR 801.109)

PREMARKET NOTIFICATION